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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,132	DHUGGA ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *13-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending and are subject to the following restriction election.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 are drawn to isolated nucleic acids, a vector, a host cell and transgenic plant/seed comprising said nucleic acid, a plant transformation method, classified in class 800, subclass 278, for example.

II. Claims 13, drawn to an isolated protein, classified in class 530, subclass 350, for example.

III. Claims 14-15, drawn to a method for modifying gene expression with Mu transposable element, classified in class 435, subclass 7.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the isolated protein of Group II can be prepared by another and materially different process than that of Group I, such as chemical synthesis. In addition, the protein of Group II and the nucleic acid of Group I are patentably distinct inventions as they are directed to a divergent products having different structure, function and effects. Proteins are composed of amino acids, while nucleic acids are composed of purine and pyrimidine units; any relationship between

nucleic acid and protein is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded protein. In the present claims, all the nucleic acid sequences of Group I do not necessarily encode all the proteins of Group II, and all the proteins of Group II are not encoded by all nucleic acids of Group I. For example, the nucleic acid of claim 1, part (g) comprises 25 contiguous bases of SEQ ID NO: 25, 27 or 29 which would not encode any of the polypeptides of Group II. Similarly, the nucleic acid of claim 1, parts (c) and (f) would not encode any of the polypeptides of Group II. The scope of the nucleic acid claims such as the DNA of claim 1 extends beyond the nucleic acids that encode the claimed polypeptides. A search of the nucleic acid of claim 1 would require an oligonucleotide search which is not likely to result in relevant art with respect to the proteins of Group II. For these reasons, the inventions of Groups I and II are patentably distinct, and searching them together would impose a serious search burden.

The invention of Group I and III are unrelated because the instant specification does not show that the isolated nucleic acid of Group I can be used in the method of Group III. The instant specification does not disclose that the method of Group I and the method of Group III would be used together. The plant transformation method and the method for modifying gene expression are unrelated, as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material, and therefore the inventions I and III are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches.

The invention of Group II and III are unrelated because the instant specification does not show that the isolated protein of Group II can be used in the method of Group III. The inventions of Groups II and III have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I and II together.

Because these inventions are distinct for the reasons set forth above and have acquired a separate status in the art as shown by their different classifications and their recognized divergent subject matter and because the literature search required for Groups I and II is not coextensive, restriction for examination purposes as indicated is proper.

During a telephone conversation with Janice Deaver on 02/28/05 a provisional election was made with traverse to prosecute the invention of Group II, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-12 are under consideration.

Claims 13-15 are withdrawn from consideration as being directed to the non-elected invention.

Claim Objections

At claim 1, "member" should be changed to --polynucleotide---, since the groups listed are polynucleotides.

Claim Rejections - 35 USC § 112

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for failing to recite the specific hybridization/wash conditions required for the claimed "stringent hybridization" conditions, part (c). Stringent conditions vary from one laboratory to another. The specification sets forth only exemplary stringent conditions, but does not clearly define Applicant's "stringent conditions" and hence it is not known what is encompassed by the claim. Dependent claims 2-12 do not obviate the rejection, and therefore are included in the rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 8 is directed to seed from a transgenic plant. The claim does not recite "transgenic seed", and therefore, reads on a product of nature. Due to chimerism, not all cells of a transgenic plant contain the transgene, and therefore, the claimed seed is indistinguishable from seed that naturally grows from a plant. It is suggested that ---transgenic--- be inserted before "seed".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling for claims limited to an isolated polynucleotide comprising SEQ ID NO: 25, 27, or 29 encoding SEQ ID NO: 26, 28, or 30, a recombinant expression cassette, plant/plant cell/ and seed comprising said polynucleotide, and a method of transforming a plant/plant cell with said expression cassette. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to an isolated polynucleotide having at least 70% sequence identity to the polynucleotide of SEQ ID NO: 25, 27, or 29, a polynucleotide

amplified from a *Zea mays* nucleic acid library using any primers which selectively hybridize under any stringent conditions to loci within SEQ ID NO: 25, 27, or 29, a polynucleotide which selectively hybridizes to SEQ ID NO: 25, 27, or 29 under high stringent conditions (no time is specified), and a polynucleotide comprising at least 25 contiguous bases of said polynucleotides. No function is recited in the claim for said polynucleotides. The claims are also drawn to a recombinant expression cassette comprising said polynucleotide in sense or antisense orientation with respect to a promoter, and a method of modulating level of cellulose synthase by expressing said polynucleotide. Transgenic plants/plant cells including specific monocot and dicot plants are also claimed.

Applicant teaches isolation of three full-length cellulose synthase genes, CesA10 (SEQ ID NO: 25), CesA11 (SEQ ID NO: 27), and CesA12 (SEQ ID NO: 29) from a library made from the zone of an elongating corn stalk internode. Applicant also teaches that each of these three genes group with other known cellulose synthase CesA genes from Arabidopsis, rice, Gossypium, Zinnia or Populus known to be involved in secondary cell wall formation (Examples 4-8, Figure 5 and Table 3). In Example 10, Applicant teaches effect of overexpression of different CesA genes on stalk strength as well as methods for measuring mechanical strength of transgenic maize stalks (Figures 6-7).

Applicant has not taught the obtention and use of all the polynucleotides of parts (a), (c)-(d), and (g) of claim 1 or their ability to modulate the level of cellulose synthase in a transgenic plant. The specification provides general guidance on determination of

sequence identity, hybridization techniques, construction of nucleic acid library, amplification and assays of testing protein activity, recombinant and plant transformation methods. However, the specification does not provide guidance with respect to how to obtain the specifically claimed polynucleotides having the ability to modulate level cellulose synthase in a transgenic plant/plant cell. Applicant has not taught how to use a transgenic plant comprising of the polynucleotide of parts (a), (c)-(d), (f), or (g) of claim 1, since no function is recited for the polynucleotide.

Assuming arguendo that a polynucleotide of part (a), (b), (c), (d), or (g) of claim 1 would encode a polypeptide having cellulose synthase activity. Applicant has not taught which region of the full-length disclosed polynucleotide has the ability to encode a functional cellulose synthase and which regions would tolerate modifications. One skilled in the art would not expect that the majority of the polynucleotides of part (a), (c), (d), or (g) of claim 1 would be functionally related to SEQ ID NO: 25, 27 or 29 because of the any " stringent conditions" and fragments as few as 25 contiguous bases, and the sequence identity of as low as 70%. The scope of the claims encompasses polynucleotides with multiple modifications including deletions, additions, and substitutions of multiple nucleotides any regions in the sequence of SEQ ID NO: 25, 27, or 29. In the absence of specific guidance for how and which region in the disclosed sequences would tolerate such modifications, one skilled in the art would have to make all possible nucleotide substitutions, deletions, and/or additions in the 3000 base pairs of SEQ ID NO: 25, 27, and 29, and test all polynucleotide sequences that meet the structural limitation to determine which also meet the functional limitation. These tests

are considered undue. Undue experimentation would also be required to evaluate the ability of each of said polynucleotide to modulate the level of cellulose synthase in a transgenic plant. It is apparent that further research not considered to be routine would be required before one skilled in the art would know how to use the polynucleotides of parts (a), (c), (d), or (g) of claim 1, to achieve a desired agronomic trait in a transgenic plant.

The instant specification is not enabling for antisense inhibition of the nucleic acids as broadly claimed in claim. The specification teaches the antisense of SEQ ID NO: 25, 27 or 29. The state of the art teaches that a high level of sequence identity must exist between the antisense nucleic acid and the target molecule for effective inhibition of expression to occur. Given the degeneracy of the code, many of the nucleic acids that encode SEQ ID NO: 26, 28, or 30 share relatively little sequence identity, and are significantly divergent from the nucleic acid of SEQ ID NO: 25, 27, or 29. Applicant provides no guidance for inhibition of nucleic acids other than SEQ ID NO: 25, 27, or 29 by antisense technology, and Applicant teaches no other target nucleic acids that are endogenous to maize. In addition, since plant cellulose synthases exist in multiple form in different plant tissues as evidenced by Applicant's own invention, the antisense expression of one nucleic acid may not inhibit the expression of all different forms of cellulose synthase in various plant tissues.

Furthermore, since the working examples disclosed in the specification are limited to unmodified SEQ ID NO: 25, 27, or 29; the ability of said polynucleotide to encode a functional cellulose synthase and modulate the level of cellulose synthase in

transgenic plants cannot be extrapolated to any fragment of 25 contiguous bases thereof, polynucleotide having at least 70% sequence identity thereof, hybridizing sequences, and any polynucleotide amplifiable from *Zea mays* nucleic acid library using any primer that selectively hybridizes thereto under any stringent conditions; absent specific guidance.

Therefore, given the breadth of the claims; the lack of guidance as discussed supra; the unpredictability with regard to sequence modifications; and the limited working examples, the claimed invention is not enabled throughout the broad scope. *In re Wands (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to all isolated polynucleotides having at least 70% sequence identity to the polynucleotide of SEQ ID NO: 25, 27, or 29, all polynucleotides amplified from a *Zea mays* nucleic acid library using any primers which selectively hybridize under any stringent hybridization conditions to loci within SEQ ID NO: 25, 27, or 29, all polynucleotides which selectively hybridize to SEQ ID NO: 25, 27, or 29 under

high stringent conditions, and all polynucleotides having at least 25 contiguous bases of said variant polynucleotides. The claims are also drawn to recombinant expression cassettes, plant/plant cells comprising said polynucleotides and a method of modulating the level of cellulose synthase by expressing said polynucleotide in a plant.

University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) states "(a) description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The claimed invention does not meet the current written description requirements for the following reasons. Firstly, Applicant has not described the composition and structure of the polynucleotides of claim 1, parts (a), (c)-(d), and (f)-(g) including the antisense sequences thereof as recited in claim 2. No function is recited for said polynucleotides. Secondly, a substantial variation in structures and function are expected among polynucleotides amplified from Zea mays nucleic acid library using any primers which selectively hybridize to loci within SEQ ID NO: 25, 27 or 29 under any stringent conditions, or polynucleotides that share only 25 contiguous bases thereof.

Thirdly, Applicant only describes three polynucleotides from a single plant species. In addition, Applicant has not described which regions in the disclosed will tolerate modifications, so that the desired polynucleotides can be obtained. Therefore, the disclosed polynucleotide sequences are not a representative number of nucleotide sequences of the genus claimed. Consequently, Applicant has not described the recombinant expression cassettes, the transgenic plant/plant cell/seeds comprising said polynucleotides, and the methods of using said polynucleotides to modulate the expression level of cellulose synthase. Therefore, in view of all the above, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed.

See also the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-12 of copending Application No. 10/209, 059. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and the patent are directed to the isolated nucleic acid sequences of SEQ ID NO: 25, 27, and 29 and variants thereof, as well as recombinant expression cassette comprising said nucleic acid in sense and antisense, host cell, and transgenic plant comprising said nucleic acids, and a method for modulating the level of cellulose synthase in a transgenic plant. The claims in the instant specification drawn to an isolated nucleic acid comprising a polynucleotide having at least 70% sequence identity to the polynucleotide of SEQ ID NO: 25, 27, or 29, a polynucleotide amplified from a *Zea mays* nucleic acid library using any primers which selectively hybridize under any stringent hybridization conditions to loci within SEQ ID NO: 25, 27, or 29, a polynucleotide which selectively hybridize to SEQ ID NO: 25, 27, or 29 under high stringent conditions, or a polynucleotide comprising at least 25 contiguous bases of said polynucleotides, recombinant cassette and transgenic plant comprising said polynucleotide and a method of transforming plant/cell with said polynucleotide, are broader in scope than the claims in the copending application drawn to an nucleic acid comprising a polynucleotide having at least 90% sequence identity to SEQ ID NO: 25, 27, or 29, recombinant cassette and transgenic plant comprising said polynucleotide and a method of transforming plant/cell with said polynucleotide. Therefore, the instantly claimed invention encompasses the invention claimed in the copending application.

Since the claims in both this application and the copending application were not divisional from restriction requirement, the obviousness double patenting rejection is proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Arioli et al (WO 98/00549).

The claims are directed to an isolated polynucleotide amplified from a *Zea mays* nucleic acid library using any primers which selectively hybridize under any stringent hybridization conditions to loci within SEQ ID NO: 25, 27, or 29. The claims are also drawn to recombinant expression cassettes, plant/plant cells comprising said polynucleotides and a method of modulating level of cellulose synthase by expressing said polynucleotide and transgenic maize, wheat, rice and soybean. Claim 1 (c) does not recite specific primers and PCR reaction conditions, and the hybridization conditions of claim 1 (d) do not specify wash time.

Arioli et al teach an isolated nucleic acid sequence from maize encoding a cellulose synthase (page 8, lines 19-21). The cited reference teaches a recombinant expression construct comprising said nucleic acid sequence operably linked to a

promoter, transgenic plants including monocot and dicot expressing said nucleic acid sequence, and a method for increasing the level of cellulose synthase in transgenic plants including maize and cotton by expressing the isolated nucleic acid sequence in sense or antisense orientation (Example 14-18 and pages 170-188). The cellulose synthase DNA from maize disclosed by Arioli would inherently comprise the polynucleotide of claim 1, absent evidence to the contrary. Therefore, Arioli et al teach all claim limitations.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/3/05

Mai

Medina A. Ibrahim

MEDINA A. IBRAHIM
PATENT EXAMINER